#17
B. Webb
11/13/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of
Rourke et al. :
Serial No. 09/529,575 : Group Art Unit:3761
Filed: July 13, 2001 : Examiner: J. Webb
Confirmation No.: 9622

Title: PROTEASE INHIBITORS IN ABSORBENT ARTICLES

DECLARATION OF SCOTT EDWARD OSBORNE UNDER 37 C.F.R.§1.132

The Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, Scott Edward Osborne, of Liberty Township, Ohio, the undersigned, declare as follows:

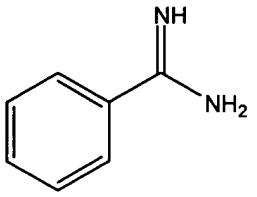
All statements made herein are true to the best of my knowledge, or, if made upon information and belief, are believed to be true.

I am a graduate of The University of Michigan having received a Ph.D. degree in bioorganic chemistry from that institution in 1996. I am also a post-doctoral fellow of Indiana University in the field of molecular biology. Since 1997, I have been employed by The Procter & Gamble Company of Cincinnati, Ohio, assignee of the present application, where I am currently a Section Head. My areas of technical specialization are chemistry, biochemistry, enzymology, and skin science.

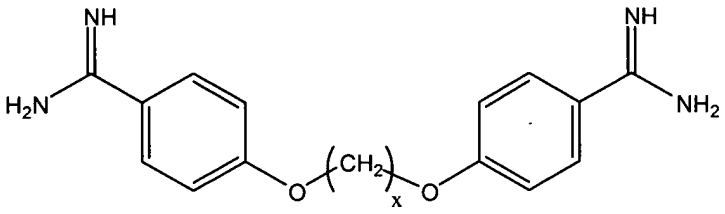
I am a co-inventor of the present application. Accordingly, I am familiar with the subject matter, including the claims of the present application.

I am also familiar with Japanese Kokai JP 04-182,423 by Kasahara et al. (hereinafter referred to as "Kasahara"), which was cited by the Examiner during the prosecution of this patent application. Moreover, I am familiar with chemicals including benzamidine, pentamidine and hexamidine, which the Office Action suggested are equivalent structures, functional-wise.

The structures of benzamidine, pentamidine and hexamidine are known in the art and are shown below for comparison.



Benzamidine



x = 5 Pentamidine
x = 6 Hexamidine

Benzamidine has a mono-benzene ring structure with one amidine $C(=NH)NH_2$ attached to it. On the other hand, pentamidine and hexamidine are within a class of molecules called aromatic diamidines, which have a dimeric structure with the diamidine-substituted benzene rings connected by a – O - $(CH_2)_X$ – O - linkage. These structural differences are significant both chemically and biologically, and they contribute to the inhibitory activities of the diamidines. The effect is shown below in an experiment carried out according to the General Fecal Protease Method disclosed in the present application.

EXPERIMENTALS AND RESULTS

The following experiments were carried out under my supervision in January 1999, which clearly distinguishes these chemicals based on their inhibitory activities. The experiments were carried out according to the test method entitled "General Fecal Protease Method", which is disclosed on page 24, line 9 to page 25, line 13 of the present application. The inhibitors used in these experiments included benzamidine, hexamidine and pentamidine. The results are shown in TABLE 1 below.

TABLE 1

	IC_{50} VALUES (μM)
INHIBITOR	**General Fecal Proteases**
Benzamidine	966
Hexamidine	31
Pentamidine	37

The results show that there are significant differences in their inhibitory activities. Therefore, pentamidine and hexamidine are not equivalent to benzamidine, functional-wise. Moreover, pentamidine and hexamidine exhibit IC_{50} values clearly within the scope of the claimed IC_{50} value of about 500 μM or less, whereas benzamdine exhibits an IC_{50} value significantly greater than 500 μM and is clearly outside the scope of the claimed invention.

Based on the foregoing, it is my expert opinion that benzamidine, and its derivatives p-aminobenzamidine or m-aminobenzamidine disclosed by Kasahara are significantly different, functional-wise, from the presently claimed pentamidine and hexamidine.

Further declarant sayeth not.

This declaration is made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and may jeopardize the validity of the above-captioned patent application or any patent issuing thereon.

10.30.02
Date

Scott Edward Osborne
Scott Edward Osborne

18 U.S.C. §1001 Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or advice a material fact, or makes any false, fictitious or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined not more than $10,000 or imprisoned not more than five years, or both.